UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IN RE BRISTOL-MYERS SQUIBB SECURITIES LITIGATION	:	Civil Action No. 00-1990 (SRC)
	:	Return Date: June 6, 2005
	:	Oral Argument Requested

LEAD PLAINTIFF'S MEMORANDUM OF LAW IN OPPOSITION TO DEFENDANTS' MOTION TO STRIKE THE EXPERT TESTIMONY OF PAUL L. STOLLEY

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Lead Plaintiff, the LongView Collective Investment Fund ("Lead Plaintiff"), respectfully submits this memorandum of law in opposition to defendants' motion to strike, pursuant to Rule 702 of the Federal Rules of Evidence, the testimony of Lead Plaintiff's expert, Dr. Paul Stolley. Defendant Bristol-Myers Squibb ("BMS" or the "Company"), along with individual defendants Charles A. Heimbold, Peter R. Dolan and Peter S. Ringrose (collectively, "Defendants"), have moved collectively for this relief.[1] Although Defendants fashion their motion as one seeking to strike Dr. Stolley's report and testimony in their entirety, in fact only particular portions of his expert opinions are being challenged. Accordingly, Dr. Stolley should not be precluded from testifying in this action and, in addition, the challenged portions of his report should not be stricken, for the reasons discussed herein.

PRELIMINARY STATEMENT

A. Background Facts

In light of the recent submission of papers in support and opposition to Defendants' motion for summary judgment and the Court's August 30, 2004 opinion, familiarity with the facts underlying the claims is presumed.

B. Dr. Stolley's Expert Opinions

[1] Lead Plaintiff's expert reports were submitted as exhibits 12-19 to the Declaration of James W. Johnson, Esq. in Opposition to Defendants' Motion for Summary Judgment, dated February 4, 2005. To the extent any exhibits cited herein were submitted in support of or opposition to Defendants' summary judgment motion, they will be referred to as either "PX" or "DX" and will bear their original summary judgment reference number. Any new exhibits, which were not submitted either in support of or opposition to Defendants' summary judgment motion, are being submitted herewith as exhibits to the Declaration of James W. Johnson In Opposition to Defendants' Motions To Strike The Expert Testimony of Lead Plaintiff's Expert Witnesses, dated May 23, 2005 ("Johnson Opp. Decl."), and are referred to as "Pl. Opp. Ex. ___."

Based on his decades of experience as an epidemiologist, and working with the FDA on new drug issues, Dr. Stolley opined on BMS' epidemiological response to the high incidence and severity of angioedema in the Vanlev clinical trials. Specifically he opined as follows:

- A responsible pharmaceutical company developing a new drug with angioedema as a side effect would monitor carefully and compare the incidence and severity with Vanlev with the incidence and severity of angioedema with other ACE-inhibitors. (PX 17 at 3.)

- After four intubations, Vanlev's safety profile was significantly worse than other ACE-inhibitors. (PX 17 at 4.)

- The intubations should have triggered an urgent response by BMS. (PX 17 at 4.)

- BMs did not carry out a scientifically credible assessment of Vanlev's angioedema risk before filing its NDA. (PX 17 at 4.) A complete review of the clinical trial experience with Vanlev should have been carried out to determine whether the angioedema seen with Vanlev was qualitatively or quantitatively different from ACE-inhibitors. (PX 17 at 6.)

- The analysis performed by the Company was deficient in several respects, which Dr. Stolley describes from an epidemiological standpoint. (PX 17 at 6.) He also describes qualitative and quantitative epidemiological analyses that BMS could have but did not perform in order to assess Vanlev's risk relative to ACE-inhibitors. (PX 17 at 8.)

- The sheer number of blinded events reported from the OCTAVE trial was excessive, and should have caused Defendants' concern. Defendants could and should have calculated the angioedema incidence from the blinded data, and presumed that the preponderance of the angioedema was in the Vanlev arm of the trial. (PX 17 at 11-12.)

- Good industry practice required Defendants to unblind the data and do the eight week safety analysis as specified in the OCTAVE trial protocol, and as represented to the FDA. (PX 17 at 11-12.)

- The risk management plan devised by Defendants was implausible and highly unrealistic. (PX 17 at 13.)

C. Dr. Stolley's Qualifications

Dr. Stolley is an eminently qualified medical epidemiologist. As described below, Dr. Stolley's professional experience makes him uniquely qualified to opine upon the

epidemiological assessment of data by a pharmaceutical company seeking FDA approval for a new drug.

1. Epidemiology Experience

Dr. Stolley is a medical doctor and medical epidemiologist who has practiced in the field of pharmacoepidemiology for nearly four decades. He has served on numerous FDA committees, including the Scientific Advisory Committee to the FDA Commissioner. (PX 17 at 2.)

Dr. Stolley was trained in epidemiology at Johns Hopkins, and worked in epidemiology at the Centers for Disease Control and the Office of the Surgeon General. He was the Acting State Epidemiologist for the Maryland State Health Department. He has also been a consultant in epidemiology to the National Institutes of Health, the Food and Drug Administration, the National Cancer Institute, the National Academy of Sciences, and the Veterans Administration. (PX 17 Ex. A at 1-2.)

He has held academic posts in epidemiology for thirty four years, including teaching courses in epidemiology at Johns Hopkins and the University of Maryland School of Medicine. He was Co-director of the Clinical Epidemiology Unit of the Department of Medicine at the University of Maryland, and later the Chairman of the University's Department of Epidemiology and Public Health. He also taught courses in pharmacoepidemiology at the University of Rotterdam and at Tulane University. (PX 17 Ex. A at 1-2.)

Dr. Stolley has been President of several national epidemiology societies, including the Society for Epidemiologic Research, the American Epidemiological Society, and the American College of Epidemiology. He was Treasurer of the International Epidemiological Association. (PX 17 Ex. A at 2.)

He was on the editorial board of the Epidemiology Monitor. He has written over 180 articles on epidemiology. He is the author of a textbook on epidemiology, as well as two books on epidemiology techniques. (PX 17 Ex. A.)

2. FDA Experience

Dr. Stolley has extensive experience working for and with the FDA. He has served on a dozen FDA committees in the past forty years, including the Scientific Advisory Committee and the FDA Biometrics and Epidemiology Advisory Committee, which reviews statistical epidemiological questions facing the FDA. (Meth Ex. 6 47:12-23, 39:8-41:2.) Dr. Stolley has served on additional FDA committees, including the FDA drug review committee for antimicrobial over-the-counter drugs; the FDA special board of inquiry for Deprovera; and the OTC drug advisory committee. (Meth Ex. 6 38:25-40:14.) He served on the FDA Committee that devised the procedures by which the Kefauver legislation would be implemented in regard to over-the-counter drugs. (Meth Ex. 6 39:13-21.)[2] In fact, at one time Dr. Stolley had a special dispensation from the Secretary for Health Education and Welfare to allow him to sit on three committees simultaneously, when the limit was two. (Meth Ex. 6 39:13-18.)

For the first eleven years of his tenure with the FDA, much Dr. Stolley's time was spent on drug pre-approval issues. (Meth Ex. 6 44:3-23.) In addition to his committee work for the FDA, Dr. Stolley has also been asked to serve as a special consultant on specific projects.[3]

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[2] The Kefauver Legislation, said to establish modern drug review and approval procedures, required drug manufacturers for the first time to prove to the FDA the effectiveness of their drugs before marketing them. www.med.howard.edu/pharmacology/handouts (last visited May 21, 2005); www.fda.gov/cder/about/history/page32.htm (last visited May 21, 2005.)

[3] At the FDA's request Dr. Stolley acted as a special consultant to review the data on an epidemic of infant deaths in France, and also on a committee to address the issue of DES and cancer. (Meth Ex. 6 42:17-43:12.)

In addition to his full time work for the FDA Center for Drug Evaluation and Research ("CDER") in 2000 – 2001, Dr. Stolley has consulted on specific issues for the CDER. (Meth Ex. 48:3-14.)

Dr. Stolley taught courses at the FDA in pharmacoepidemiology to the FDA staff. His courses included aspects of drug pre-marketing approval, including how to calculate risk and benefit, and how to weigh risk and benefit in the pre-approval context. (Meth Ex. 6 49:3-51:12.) In 2000-2001 he also taught at the FDA, together with Dr. David Graham, a course for the medical officers, many of whom were in the pre-marketing or drug approval group, on the epidemiology of drugs. (Meth Ex. 6 49:19-50:11.) Because many of the FDA medical officers taking Dr. Stolley's and Dr. Graham's course were from the FDA drug pre-approval branches, there was a fair amount of emphasis on pre-approval issues. The curriculum covered the full range of epidemiological issues that were relevant to the staff's day to day work. (Meth Ex. 6 52:10-21, 53:14-17; Pl. Opp. Ex. 6 53:17.)

Dr. Stolley also has expertise in evaluating risk management plans. At the FDA's request, Dr. Stolley consulted on a risk management plan for the drug Lotronex. (Meth Ex. 6 53:18-54:8.)

Dr. Stolley also worked at Public Citizen consulting on FDA matters. (Meth Ex. 6 228:14-19.)

3. Clinical Trial Experience

Dr. Stolley has served on the Data Safety Monitoring Boards of at least two randomized clinical trials, and for thirty years has been on the board of directors for the Maryland Medical Research Institute, a not-for-profit research institute that does analysis and sets up DSMBs for clinical trials for the government and the pharmaceutical industry. (Meth Ex. 6 76:21-78:7, 81:10-83:6.) He has acted as a consultant for a pre-approval randomized control clinical trial,

and has reviewed the work of adjudication committees of randomized controlled clinical trials. (Meth Ex. 6 83:15-84:20; 88:7-11.)

4. Relevant Medical Experience

Dr. Stolley has an active practice in internal medicine. He has treated patients continuously for the past thirty years.[4] Approximately 40% of his patients over the past thirty years have had hypertension, which he has treated. (Meth Ex. 6 15:8-16:13.)

Dr. Stolley had an understanding of angioedema before he was retained to work on this case. He served on the Advisory Committee and the DSMB of a five-year international study of angioedema. (Meth Ex. 6 26:15-27:17.)

D. Defendants' Motion to Strike Dr. Stolley's Expert Testimony

Ignoring Dr. Stolley's extensive relevant experience with the FDA and as an epidemiologist, Defendants argue that his entire expert report should be excluded because his opinions are "based solely on Dr. Stolley's subjective beliefs and haphazard intuition . . . ," and because his opinions will not assist the trier of fact. (Def. Mem. at 1.) They argue that his opinions are based on unreliable methodology, that none of his opinions "fit" the facts of this case. (Def. Mem. at 8-9, 10-11, 15-16.) They argue his opinions are more prejudicial than probative and must be excluded under Rule 403. (Def. Mem. at 6-8, 9-15, 17-18.) Defendants' motion must be denied in full, for the reasons explained below.

[4] Dr. Stolley currently treats patients at the University of Maryland School of Medicine Faculty Practice, and as a paid volunteer at the county clinic for the uninsured. In the past, he treated patients at Johns Hopkins and while he was with the Public Health Service. For several summers he treated children and adults on a Navajo reservation. (Meth Ex. 6 11:12-14:23.)

ARGUMENT

I. Legal Standards Governing Admission of Expert Testimony

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony and provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702. The rule was amended in 2000 in response to Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579 (1993), and to the many cases applying Daubert, including Kumho Tire Co. v. Carmichael, 526 U.S. 137 (1999), and General Elec. Co. v. Joiner, 522 U.S. 136, 140 (1997). More recently, in Schneider v. Fried, 320 F.3d 396, 405 (3d Cir. 2003), the Third Circuit described these requirements as the "trilogy of restrictions on expert testimony: qualification, reliability and fit."

In Elcock v. Kmart Corp., 233 F.3d 734, 741 (3d Cir. 2000), the Third Circuit re-affirmed the liberal standard for qualifying an expert in the Third Circuit:

> Rule 702 requires the witness to have 'specialized knowledge' regarding the area of testimony. The basis of this specialized knowledge 'can be practical experience as well as academic training and credentials.' We have interpreted the specialized knowledge requirement liberally, and have stated that this policy of liberal admissibility of expert testimony 'extends to the substantive as well as the formal qualification of experts.' However, 'at a minimum, a proffered expert witness … must possess skill or knowledge greater than the average layman…'(citing Waldorf v. Shuta, 142 F.3d 601, 625 (3d Cir. 1998))

As described below, Dr. Stolley's report and testimony easily meet these standards.

II. Dr. Stolley's Opinions on BMS's Epidemiological Investigation of the Incidence of Angioedema

A. Dr. Stolley's Opinions on BMS's Epidemiological Investigation of the Incidence of Angioedema are Reliable

Dr. Stolley opines on the appropriate qualitative and quantitative epidemiological analysis that should be conducted by a pharmaceutical company developing an experimental drug that has a known serious adverse side effect. He also opines that the epidemiological analysis that BMS undertook was deficient in several respects. Dr. Stolley's opinions are cloaked in the hallmark indicia of reliability.

Defendants' argument that Dr. Stolley's opinions regarding BMS's investigation of the incidence of angioedema are based "solely on Dr. Stolley's subjective beliefs and intuition. . ." is entirely wrong. (Def. Mem. at 6.) In assessing the inadequacies of BMS's epidemiological inquiries into the comparative incidence and severity of angioedema in the Vanlev clinical trials, Dr. Stolley drew upon four decades of experience as a medical epidemiologist, including analyzing FDA pre-approval clinical trial issues.

In determining the adequacy of BMS's analysis of the comparative incidence of angioedema, he considered BMS's written analyses, and other documents in this case that reflect the analysis that BMS did and did not perform. (PX 17 Ex. B; Meth Ex. 6 68:4-25, 70:4-19.) He applied his indisputably pertinent experience in clinical trials, FDA pre-marketing approval, angioedema and epidemiology to the facts of the case, as reflected in appropriate documents.[5] He then rendered an opinion on the appropriate epidemiological measures that BMS could have

[5] Defendants do not challenge, or even mention, Dr. Stolley's expert qualifications.

taken to learn the comparative incidence and safety of Vanlev, as well as the ways in which the analysis that BMS performed was deficient.[6]

Defendants do not point to any specific type of methodology, or test, or analysis that Dr. Stolley neglected to perform that renders his opinion unreliable. They do not identify critical documents that he did not consider. Nor do they claim that his methodology is wrong, or based on false assumptions. The cases Defendants cite are illustrative. In Zenith Electronics Corp. v. WH-TV Broadcasting Corp., 395 F.3d 416, 419 (7th Cir. 2005) for example, the issue was the amount of damages from the loss of potential subscribers to Direct TV. The proffered expert did not perform a multivariate regression, which is the standard analysis widely used in that type of case, nor did he explain why he had not done so. That is not the case here.

Defendants incorrectly claim that Dr. Stolley does not disclose the source of his opinions as to good industry practice, or good clinical trial practice,[7] and that his opinions are therefore subjective and must be excluded. (Def. Mem. at 6-7, 13-14.) In fact his deposition testimony was replete with references to the sources for his opinions about the industry standard for pre-approval epidemiological analysis of clinical trial data. He testified that his sources included the following: The book on clinical trials by Dr. Curt Meinert, (Controlled Clinical Trials, 3rd Edition) which discusses the general conduct of a clinical trial, the interpretation of clinical trial results, whether there is standardized collection of data, reasons for stopping the study, as well as

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[6] Defendants claim that Dr. Stolley improperly opines on epidemiological measures that the Company "should have taken." Dr. Stolley will testify as to the industry standard epidemiological analysis for a pharmaceutical company in clinical trials seeking FDA approval. He is also permitted to compare the industry standard with the Company's epidemiological analysis. Smith v. Wyeth-Ayerst Labs., 278 F. Supp. 2d 684, 702 (W.D.N.C. 2003). If the Court determines that use of the word "should" is improper, the witness can be directed not to use it.

[7] Dr. Stolley explained that he used the terms good clinical practice and good clinical trial practice interchangeably. (Meth Ex. 6 109:8-16.) His references to good industry trial practice also referred to good industry practice. (Meth Ex. 6 160: 6-17.)

the ethical considerations for clinical trials (Meth Ex. 6 88:14-89:15; 110:10-111:6; 190:17-191:3, 195:11-196:8); various conventions that deal with the problem of adverse events discovered in clinical trials, including conventions established by the World Health Organization, and the National Institutes of Health ethical rules on clinical trials practice, (Meth Ex. 6 110:23-112:19);[8] his own experience on data safety and monitoring committees and as an epidemiologist with experience in the area of the response required after the report of an adverse event in a clinical trial, his experiences with many similar incidences, and his years of experience dealing with adverse drug reactions. (Meth Ex. 6 113:1-11, 115:3-116:21, 119:12-120:8.) He testified that the NIH and WHO standards above-referenced describe the research ethics that delineate the obligation in a clinical trial to continue in an ongoing analysis and have a clearly stated stopping rule when concerned about the toxicity of a drug. Dr. Stolley testified that he also bases his opinions about what should be done quantitatively and qualitatively to evaluate adverse events and clinical trial databases on some of his own textbooks, including a chapter he wrote in the Strom textbook of phamacoepidemiology, first and second editions, and chapter 6 or 7 in the textbook Paul Stolley and Tamar Lasky, Investigating Epidemics: The Science of Epidemiology; W.H. Freeman Press, 1996. (Meth Ex. 6 120:9-121:3.)[9]

Defendants argue that Dr. Stolley applies the industry practice standard unreliably, because while he testified that pharmaceutical companies should conduct themselves according

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[8] Dr. Stolley could not recall the precise wording of the title of the NIH rules on clinical trial practice. (Meth Ex. 6112:7-16.)

[9] Dr. Stolley was asked the sources for good industry practice and for what good clinical trial practice entails. (Meth Ex. 6 110:10-11, 162:9-10.) Counsel did not produce the textbooks he identified during his deposition in accordance with the agreement of counsel that the parties would produce "all of the materials considered or relied upon specifically for purposes of the expert's report that are not otherwise generally part of his or her expertise . . ." (Pl. Opp. Ex. 12.) The materials Dr. Stolley identified were part of his general expertise, not materials specifically relied on in purposes of his report.

to good industry practice prior to testing drug on humans, he opines on Defendants' conduct while clinical trials were ongoing, as opposed to before they began. (Def. Mem. at 7.) The argument is unavailing. Dr. Stolley certainly did not say that pharmaceutical companies can freely disregard good industry trial practice as soon as the first patient is enrolled in the clinical trial.

The cases cited by Defendants wherein courts excluded expert testimony are very different from this case. In Hall v. Baxter Healthcare Corp., 947 F. Supp. 1387, 1406 (D. Or. 1996) the Court excluded expert testimony that "inexplicably" directly contradicted the general consensus of the relevant scientific community.

In Oddi v. Ford Motor Co., 234 F.3d 136 (3d Cir. 2000) the Court noted that "the standard for determining scientific reliability 'is not that high.' The test is not '[w]hether the . . . expert might have done a better job.' . . . the Federal Rules of Evidence 'embody a strong and undeniable preference for admitting any evidence which has the potential for assisting the trier of fact'." Oddi, 234 F.3d at 156 (internal citations omitted). Nonetheless the Court found it was proper to exclude the testimony of a proffered expert in crashworthiness who admitted that he did not even consider certain important design factors, and whose explanation of the purported defect was undermined by the laws of physics. Oddi, 234 F.3d at 157.

In Fireman's Fund Ins. Co. v. Canon U.S.A., Inc., 394 F.3d 1054 (8th Cir. 2005) the opinions of fire causation experts were excluded where their conclusions were based on experimental testing that did not meet the standards established by the National Fire Protection Association, and the experts' theory did not reconcile with the empirical evidence. Id. at 1058-1059.

In this case, unlike those Defendants cited, there is no suggestion that Dr. Stolley's opinion contradicts the widely held consensus of the epidemiological or FDA communities, or that his testimony was undermined by the laws of epidemiology. Defendants' cases do not support their argument that Dr. Stolley's opinion should be excluded.

B. Dr. Stolley's Opinion About Defendants' Epidemiological Efforts Fit the Facts of This Case

To be admissible an expert's testimony must "fit" the facts of the case, in that it must assist the trier of fact. Under the "fit" requirement, admissibility depends on the connection between the opinion to be presented and the particular facts of the case. "This standard is not intended to be a high one." Oddi, 234 F.3d at 145. In In re Paoli R.R. Yard PCB Litig., 35 F.3d 717 (3d Cir. 1994) ("Paoli II") the Court explained that the ultimate touchstone of reliability is helpfulness to the trier of fact, which turns on whether the expert's principle is sufficiently reliable so that it will aid the jury in reaching accurate results. The Court then said: "The same standard of reliability extends to the step in the expert's analysis that 'fits' his or her conclusions to the case at hand. Once again we emphasize that the standard is not that high." Paoli II, 35 F.3d at 745-6.

Based on his decades of experience and learning in epidemiology and FDA pre-approval issues, Dr. Stolley opined on the proper epidemiological analysis that should be conducted when a pharmaceutical company conducting human trials of an experimental drug encounters a high incidence of life threatening adverse events. The trier of fact in this case must determine whether Defendants' statements to the effect that Vanlev's incidence of angioedema and its safety profile were comparable to those of other ACE-inhibitors were true, or whether they were knowingly or recklessly false. Dr. Stolley's expert opinion about the epidemiological steps that BMS could have but did not take to accurately assess Vanlev's incidence and safety profile will

assist the jury greatly in making that determination. "An egregious refusal to see the obvious, or investigate the doubtful, may in some cases give rise to an inference of recklessness." GSC Partners CDO Fund v. Washington, 368 F.3d 228, 239 (3d Cir. 2004).

Defendants' argument, that Dr. Stolley's opinion as to the appropriate epidemiological analysis BMS should have made in response to the reports of intubations is an improper focus on a negligence or malpractice standard, misses the point, as does their citation to In re TMI Litig., 193 F.3d 613 (3d Cir. 1999). In TMI the proffered expert testimony of a meteorologist did not "fit" the facts of a case wherein the issue was whether plaintiffs' exposure to radiation from the nuclear reactor accident at Three Mile Island caused their neoplasms. The excluded testimony concerned a water model that the meteorologist admitted did not simulate the radiation flow at the time of the accident. Thus, the water model did not "fit" the facts of the case, and was not helpful to the jury. TMI, 193 F.3d at 670-671.[10]

Dr. Stolley's opinions, by contrast, precisely dovetail with the facts of this case.

III. Dr. Stolley's Opinions on Vanlev's Safety Profile

A. Dr. Stolley Opinions on Vanlev's Safety Profile are Reliable

1. Dr. Stolley Correctly Focused on Life Threatening Angioedema in Assessing Vanlev's Safety Profile

Dr. Stolley opined that contrary to defendants' statement that Vanlev had a safety profile comparable to leading hypertension therapies, in fact its safety profile was significantly worse, because Vanlev patients were vastly more likely to develop severe angioedema, including cases leading to intubation and/or tracheotomy. (PX 17 at 4.) Dr. Stolley testified that, in determining whether Vanlev's safety profile was worse than that of other antihypertensives, his "main

[10] As to another model, a "plume movie," the meteorologist testified that it was "an assumption . . . more than a provocation. . . . I just don't have enough of a database to provide details of this." TMI, 193 F.3 at 670.

concern was in serious life-threatening events, not the more common, but less serious reactions that you see with all drugs, even placebos." He focused mainly on angioedema "[b]ecause that was the adverse event of great interest and which was a main concern during drug development phase." (Meth Ex. 6 73:7-22.) He did not see any side effects other than angioedema that he considered to be serious or life threatening when he looked at the Vanlev clinical trial data. (Meth Ex. 6 74:9-13.) Defendants argue that Dr. Stolley's methodology is unreliable because he focused on life threatening angioedema in his assessment of Vanlev's safety profile, rather than on less serious side effects. (Def. Mem. at 9-10.) The argument makes no sense. Consideration of "common, less serious reactions that you see with all drugs, even placebos" would not ameliorate the fact that the incidence and severity of life threatening angioedema was greater in Vanlev than other antihypertensives. If Defendants want to argue otherwise, the place to do so is in cross-examination, not on a Daubert motion.

2. Dr. Stolley Disclosed the Sources of His Opinions About the Incidence of Angioedema

As for Defendants' argument that Dr. Stolley's opinions must be excluded because he did not describe the sources of his opinions about the incidence of angioedema with ACE-inhibitors, they are mistaken. (Def. Mem. at 10.) Dr. Stolley was not asked that question at his deposition, but in response to other questions, he testified that he reviewed several comparative analyses of the incidence of angioedema with ACE-inhibitors, including the reports prepared by Wayne Ray,

by David Lilienfield, and by Joanna Whyte, as well as the FDA's comparative analysis. (Meth Ex 6 68:14-25; 70:4-19.)[11]

This case is very different from Pappas v. Sony Electronics, Inc., 136 F. Supp. 2d 413 (W.D. Pa. 2000), which Defendants cite in support of their argument that Dr. Stolley did not provide sufficient evidence of his methodology. In Pappas, plaintiff's expert opined on the cause of a fire. The expert acknowledge that the theory of causation that was the basis for his opinion had been peer reviewed and rejected by the National Fire Protection Agency.

There is no similar evidence in this case that the theory underlying Dr. Stolley's opinion has been rejected by the FDA or the National Association of Epidemiologists.

B. Dr. Stolley's Opinion About Vanlev's Safety Profile Fit the Facts of this Case

Defendants state that a question for the jury in this case is whether BMS had a reasonable basis for its statements that the Vanlev incidence of angioedema was comparable to other ACE-inhibitors. (Def. Mem. at 11.) Lead Plaintiff disagrees with this formulation. The question for the jury is whether Defendants had actual knowledge of the false or misleading nature of their representations, or whether they acted recklessly regarding their representations or omissions. In making that determination, the trier of fact will consider BMS's epidemiological analyses of the Vanlev data vis-à-vis the angioedema experience with other ACE-inhibitors. Defendants do not dispute that Dr. Stolley is an expert in this area. His testimony as to the appropriate

[11] Contrary to Defendants' representation, Dr. Stolley did not testify that his opinions about angioedema were based on textbooks he did not produce. (Def. Mem. at 10.) He testified that in preparing his report, he did not consider materials other than those identified in his report. He did do some general research in preparing to write the report. He looked at "major textbooks in medicine," which he identified at his deposition. (Meth Ex. 6 7:6-10:10.) Pursuant to agreement with counsel, Lead Plaintiff did not produce the textbooks because they were not specifically relied on by Dr. Stolley in preparing his expert report, and were part of his general expertise. (Pl. Opp. Ex. 12.)

epidemiologic measures of disease incidence with an experimental drug in human trials is a precise "fit" with the issues in this case.

Defendants' argument, that Dr. Stolley's opinions do not fit the facts of this case because the FDA allegedly did not conclude that BMS' investigation was improper, has nothing to do with Daubert "fit."[12] It is a matter for cross-examination at trial.

IV. Dr. Stolley's Opinions About the Blinded Data

When the FDA learned of the high incidence of angioedema and of severe angioedema in the pre-OCTAVE Vanlev clinical trials, it expressed serious concern, and BMS withdrew the NDA. (Lead Plaintiff's Statement Pursuant to Rule 56.1[13] ¶¶ 302, 334, 336-7, 342, 345-6, 358-9, 370-1.) Knowing that Vanlev had a high risk of life threatening angioedema, BMS commenced OCTAVE, a safety trial, to test the premise that the risk of angioedema could be controlled if patients were started on 10 mg doses, then titrated to higher doses. (Rule 56.1 ¶ 414.)

The OCTAVE protocol assumed that if patients began Vanlev on a reduced dose of 10 mg., the incidence and severity of angioedema would be no worse than twice that observed with enalapril, an ACE-inhibitor with an incidence of approximately 0.4% (Rule 56.1 ¶ 414-5.) In other words, Defendants' expectation and primary safety hypothesis was that the incidence of angioedema in OCTAVE would be approximately 0.4% with enalapril, and no greater than 0.8% with Vanlev.

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[12] Defendants' argument that at some point BMS gave the FDA the information it needed to review the drug is not probative of whether Defendants gave appropriate information to investors. Further, Defendants incompletely cite Dr. Grimm's testimony. Dr. Grimm clarified that his testimony that he didn't think BMS intentionally tried to mislead the FDA referred only to the safety report submitted after the first intubation. (Meth Ex. 4 234:12-235:14.)

[13] Hereinafter, references to Lead Plaintiff's Statement Pursuant to Rule 56.1 will be indicated as "Rule 56.1."

Defendants closely monitored the angioedema events in OCTAVE. Regular confidential internal memoranda reported the ongoing number of angioedema events to senior BMS management. (Rule 56.1 ¶¶ 427-9, 432, 466.) By Spring 2001, Defendants knew, based on the blinded data in these reports, that the incidence of angioedema was excessive and there were numerous cases of severe angioedema, including one intubation. (Rule 56.1 ¶¶ 464-9.)[14] BMS did not refile the Vanlev NDA based on the eight-week safety data (as the OCTAVE protocol specified and the FDA expected), but postponed refiling until the 24-week efficacy endpoints had been reached. (Rule 56.1 ¶¶ 476-84.)

Dr. Stolley opined, based on his knowledge and experience in epidemiology, clinical trials, and FDA pre-approval issues, and his review of the BMS internal management angioedema reports, that: (1) the sheer number of blinded events reported to BMS was excessive and should have caused the company concern; and (2) BMS should have unblinded the data and performed the eight-week safety analysis consistent with the OCTAVE protocol and its representations to the FDA. (PX 17 at 11-12.)

A. Dr. Stolley's Opinions About BMS's Response to the Blinded Data are Reliable

Defendants claim that Dr. Stolley's methodology is unreliable because even had they attempted to analyze the blinded data, they could not have learned the precise incidence of angioedema in the Vanlev arm of the OCTAVE trial. Dr. Stolley's point is that had Defendants performed even a rudimentary analysis of the blinded data, they would have learned that there

[14] At an emergency meeting on April 13, 2001, BMS senior-management discussed whether BMS should refile the NDA with the eight-week or 24-week data. Handwritten notes of the meeting note: "Risk vs benefit unblind now risk higher than benefit; more obligation to announce," and that the "Pattern of angioedema combined data does not fulfill prior hypotheses not favorable." (Rule 56.1 ¶ 482)

was a strong risk that the incidence and severity of angioedema in the Vanlev trial arm was much greater than anticipated. The fact that Defendants may not have been able to ascertain the precise incidence of angioedema is beside the point. This argument is wholly unavailing, and while Defendants may wish to use it in argument at trial, it is not an appropriate Daubert challenge.

The "flawed steps" that Defendants criticize in Dr. Stolley's analysis are not flawed at all. The internal BMS angioedema report, that Dr. Stolley testified about, the March 22, 2001 BMS internal angioedema report that showed that the actual angioedema rate was far in excess of what was expected. The report shows 414 angioedema events out of a trial population of 15,260 on March 21, 2001. The BMS internal report explicitly states that if the angioedema event rate for the trial were 1.5%, there would be 369 cases of angioedema. (PX 179.) By March 2001, Defendants were clearly on notice of a dramatically excessive rate of angioedema.

Defendants argue they could not have known that the high angioedema rate was not attributable to the enalapril arm of the trial, because there had not been a trial that defined a statistically significant incidence of angioedema with enalapril. (Def. Mem. at 13.) Again, Defendants argue that they should not have analyzed the blinded data because the analysis might not give perfect results. Defendants own in-house research showed an incidence rate of angioedema for enalapril. (PX 183.) Defendants could easily use these sources as a guide to the expected incidence of angioedema with enalapril, which would lead them to reasonably suspect that the excessive incidence in OCTAVE was due to Vanlev.

Defendants' also claim that they could not properly make any inferences about the blinded data because it contained both adjudicated and unadjudicated events. (Def. Mem. at 13.) The possibility that one or more of the 414 reported cases of angioedema might subsequently be

determined to not, in fact, be angioedema, does not mean that Defendants could not have learned by analyzing the blinded dated in the manner described by Dr. Stolley, that the incidence of angioedema was vastly greater than expected.

B. Dr. Stolley's Opinions About the Blinded Data Fit the Facts of This Case

Dr. Stolley's opinion that Defendants' failure to unblind and analyze the eight-week data in accordance with its representations to the FDA was a breach of good industry trial practice will assist the trier of fact in determining whether Defendants' second class period statements about Vanlev's clinical profile and blockbuster potential were made in good faith or were intentionally or recklessly false. His expert opinion that good industry trial practice would be to analyze the unblinded data, then unblind the data, gives the trier of fact information about whether Defendants had a good faith belief that Vanlev would be a blockbuster, or whether it knew that Vanlev's angioedema incidence and severity was unacceptably excessive and chose to ignore and/or conceal that information. Again, Dr. Stolley's opinion is directly related to the issues to be decided in this case.

V. Dr. Stolley's Opinion About BMS's Risk Management Plan

After Defendants announced the OCTAVE results, by the time the Cardiovascular and Renal Drugs Advisory Committee Advisory Committee met to consider the Vanlev NDA, BMS was no longer seeking approval for broad hypertension labeling. Instead it sought approval for use in a very limited subpopulation of hypertensive patients. (Rule 56.1 ¶ 606.) BMS also submitted a new proposed label that included a black box warning cautioning against use in African Americans. (Rule 56.1 ¶ 572.) Recognizing that the high incidence and severity of angioedema with Vanlev meant it was not approvable for the broader hypertension market, BMS also proposed a Risk Management Plan in hopes of getting FDA approval.

The Risk Management Plan required, in part, the following:

1. The prescriber (i.e., medical doctor) would select appropriate hypertension patients for Vanlev based on information provided through educational programs conducted or sponsored by BMS.

2. Prescribers would then counsel patients selected for Vanlev therapy on the benefits and risks of Vanlev.

3. Prescribers would inform patients that enrollment in a telephonic pharmacist-to-patient counseling programs was a mandatory prerequisite to having a prescription for Vanlev filled.

4. Prescribers then would provide the patient with a Vanlev prescription, perhaps of a short (5 to 7 day) duration. All patients receiving prescriptions would be told that they must enroll immediately in a pharmacist-counseling program.

5. Patients would call a toll free number and ask to speak with a pharmacist. The pharmacist would then ask the patient a series of questions and assess the patient's comprehension of the risk information. The pharmacist would then provide remedial instruction as required.

6. The counseling pharmacist would then provide a code number to the patient.

7. The counseling pharmacy would notify the patient's healthcare professional that the patient had successfully enrolled in the program.

8. Before filling the prescription, the retail pharmacist would call a toll free number to verify the code number presented by the patient.

9. The counseling pharmacist would convey to the retail pharmacist any potential use concerns for the particular patient.

10. The retail pharmacist would use his or her professional judgment to determine whether the patient's healthcare professional should be contacted about patient concerns for the specific patient.

11. If the patient presents a prescription without a code number, the retail pharmacist would call the counseling service to retrieve the code (for previously enrolled patients) or instruct the patient on how to enroll.

12. The retail pharmacist would provide the patient additional information on risk management as appropriate.

13. The retail pharmacist would fill the prescription.

14. Additional steps would have to be taken to refill a prescription.
(Meth Ex. 18 at VNLV 6958-960.)

A. Dr. Stolley's Opinion About BMS' Risk Management Plan is Reliable

Based on his review of the Risk Management Plan, and drawing on his expertise in evaluating risk management plans, Dr. Stolley opined that Defendants' risk management plan was highly unrealistic and implausible. (PX 17 at 13.) Defendants' argument that Dr. Stolley's opinion is "intuition" is wrong. (Def. Mem. at 17.) In addition to his expertise in epidemiology and FDA drug approval issues, Dr. Stolley is experienced in evaluating pharmaceutical company risk management plans. He was chair of the committee that the Sloan Epidemiology Group set up under contract to Roche to monitor whether or not patients and physicians were following the risk management plan for Accutane. (Meth Ex. 6 30:10-17.) The FDA was very concerned about the risk management plan for this drug, because if taken by a pregnant woman in the first trimester, it produces serious and perhaps fatal malformations. This study went on for ten years. (Meth Ex. 6 30:10-31:9.) The Accutane study showed very poor compliance with the risk management plan. (Meth Ex. 6 203:3-8.)

Dr. Stolley was also asked by the FDA to comment on the risk management plan for Lotronex. (Meth Ex. 6 53:18-54:14.) In Smith v. Wyeth-Ayerst Labs., 278 F. Supp. 2d 684, 701 (W.D.N.C. 2003), the expert, who had extensive FDA experience, reviewed testimony from the FDA Advisory Committee hearings, as well as the medical literature in forming his opinion. The Court said: "The Court takes judicial notice that this process is not unusual, but rather is precisely how many experts go about developing an opinion within their disciplines." 278 F. Supp. 2d at 701.

B. Dr. Stolley's Opinions About BMS's Risk Management Plan Fits the Facts of This Case. Lead Plaintiff Will be Prejudiced if it Cannot Rebut Testimony on the Same Subject From Defendants' Experts

Defendants' proffered experts opine that Vanlev's risk management plan was viable and would not hinder the drug's potential to achieve commercial success. For example, Dr. Elizabeth Ofili discusses Vanlev's risk management plan at length in her expert report, and concludes that the plan was viable and well designed. (DX 21 ¶¶ 111-116.) Dr. William White opines that the risk management plan would not have been a major impediment to the widespread prescription of Vanlev, and that it would not have prevented Vanlev from becoming a commercial success. (DX 27 at ¶ 83 and n. 5.)

Defendants now claim that Dr. Stolley's opinion that the Vanlev risk management plan was unworkable does not "fit" this litigation and does not relate to any issue in this case because it was submitted to the FDA after the alleged misstatements. Defendants cannot proffer their own expert testimony that the plan was viable then exclude Lead Plaintiff's contrary testimony on precisely the same subject as irrelevant.

An important issue in the case is whether Defendants believed that Vanlev would be a blockbuster, or whether their omissions and misrepresentations were knowingly false or reckless. Defendants dramatically curtailed the market for Vanlev by proposing a black box warning for African Americans, by seeking a restricted approval from the FDA for cases of severe hypertension with complicating factors, and by imposing a very complicated multi-step risk management plan that physicians, pharmacists and patients would have to comply with to prescribe the drug. The impact of these measures on Vanlev's potential for commercial success will be litigated at trial. They are not the proper subject of a Daubert motion.

Further, expert testimony on the provisions of the risk management plan are necessary rebuttal in the face of Defendants' proffered expert testimony that the plan was workable and would not negatively impact sales.

VI. Dr. Stolley's Expert Opinions Should not be Excluded Under Rule 403

Defendants seek to exclude Dr. Stolley's opinions about Defendants' epidemiologic investigation of angioedema, Vanlev's safety profile, and what Defendants could have ascertained from the unblinded data under Rule 403 on the grounds that they are more prejudicial than probative. Specifically defendants claim that Dr. Stolley's use of the terms good industry practice, good trial practice, and research ethics will substantially and unfairly prejudice and confuse the jury. (Def. Mem. at 8-9.)

A. Dr. Stolley's Opinions about Industry Practice are Highly Relevant to the Critical Issue in This Case

A critical question for the jury in this case will be whether Defendants statements were true, whether Defendants possessed conscious knowledge of their falsity, or whether the statements were made with reckless disregard. Lead Plaintiff can show conscious misbehavior by adducing facts that defendants had actual knowledge that their statements were false or misleading at the time they were made. GSC Partners CDO Fund v. Washington, 368 F.3d 228, 238-39 (3d Cir. 2004). Recklessness can by shown by "defendants' knowledge of facts or access to information contradicting their public statements." Novak v. Kasaks, 216 F.3d 300, 308 (2d Cir. 2000); In re Nice Sys., Ltd. Sec. Litig., 135 F. Supp. 2d 551, 585 (D.N.J. 2001) (same). A reckless statement is "a material misrepresentation or omission involving not merely simple, or even inexcusable negligence, but an extreme departure from the standards of ordinary care, and which presents a danger of misleading buyers or sellers that is either known to the defendant or is so obvious that the actor must have been aware of it." GSC Partners, 368 F.3d at 239. "An

egregious refusal to see the obvious, or investigate the doubtful, may in some cases give rise to an inference of recklessness." In re Nice Sys., 135 F. Supp. 2d at 585.

Lead Plaintiff will offer the testimony of Dr. Stolley to inform the jury of the ordinary standard of care for a pharmaceutical company conducting clinical trials of an experimental drug with known serious adverse side effects. The jury's task will be to determine whether Defendants' conduct in the epidemiologic analysis of the incidence and safety profile of angioedema was an extreme departure from the standard of ordinary care. In order to make that determination, the jury will need to know the standard of industry practice.[15] Dr. Stolley, whose expertise in the field of epidemiology and FDA pre-approval epidemiology is unchallenged, is well qualified to give the jury that essential information.

Defendants claim that Dr. Stolley's opinions about the epidemiological analysis that was required by industry practice and good trial practice must be excluded as irrelevant, and are more prejudicial that probative, relying on the court's decision in In re Rezulin Prods. Liab. Litig., 309 F. Supp. 2d 531 (S.D.N.Y. 2004). That case is wholly distinguishable. Rezulin is a products liability/personal injury case brought against the manufacturer of Rezulin, a diabetes drug that allegedly caused liver failure. Plaintiffs' experts opined that the drug manufacturer acted in an unethical manner in conducting the Rezulin clinical trials. The Court excluded the testimony for reasons that are not applicable here.

First, the issue for the trier of fact in Rezulin was whether defendants had breached their legal duties in manufacturing, labeling and marketing the drug. Rezulin, 309 F. Supp. 2d at 544.

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[15] In FDIC v. Refco Group, Ltd., 184 F.R.D. 623 (D. Colo. 1999) the Court permitted expert testimony on the standards of care in the insurance industry as directly relevant to plaintiff's claims for intentional misconduct and breach of fiduciary duty. 184 F.R.D. at 629-630.

The Court found that under those facts, expert opinion as to the ethics of defendants' actions was irrelevant. There is no scienter requirement in a products liability action. In this case Dr. Stolley's expert opinion on industry standards is directly relevant to a primary issue in the case -- whether Defendants' failure to conduct an appropriate epidemiological analysis was such an extreme departure from the standards of ordinary care as to give rise to an inference of recklessness. In re Nice Sys., 135 F. Supp. 2d at 585.

Second, the expert witnesses in Rezulin admitted that their opinions concerning proposed ethical standards were based not on any expertise, but on their own personal subjective views. The Court found that their opinions did not meet the core requirement that expert testimony rest on "knowledge." 309 F. Supp. 2d at 543. Here by contrast, Dr. Stolley has forty years experience in epidemiology and more than thirty years experience with the FDA. He spent at least eleven years with the FDA dealing with drug pre-approval issues. He has written textbooks on epidemiology. He taught courses to FDA medical officers on epidemiology in drug pre-approval. (Meth Ex. 6 49:3-51:12.) Unlike the testimony about ethics in Rezulin, his testimony about industry standards is firmly rooted in specialized knowledge.

The decision in In re Diet Drugs Prods. Liab. Litig., No. MDL 1203, 2001 WL 454586 (E.D. Pa. Feb. 1, 2001) is similar to Rezulin, and not applicable here. The pertinent issues in Diet Drugs were the obligations of a pharmaceutical company in testing, surveying and labeling medications. The Court excluded plaintiffs' expert testimony about medical ethics for the same reasons as did the Rezulin court: Medical ethics were not probative of the issues in the case, and the witness did not have sufficient knowledge to qualify him to opine on medical ethics of pharmaceutical companies. The Court noted that pharmaceutical company conduct is governed by extensive regulations of which the expert had little or no knowledge, and that the expert

lacked experience with FDA regulations. In this case, by contrast, Dr. Stolley has extensive knowledge of pharmaceutical company conduct as well as extensive, directly relevant, FDA experience.

The decision in Smith v. Wyeth-Ayerst Labs., 278 F. Supp. 2d 684 (W.D.N.C. 2003) is instructive. There a proffered expert who had served as a member of the FDA Cardio-Renal Advisory Committee, had participated in clinical trials evaluated by the FDA, and had served as a clinical trial consultant, was permitted to testify about the applicable standard of care for reporting adverse drug events. Id. at 701 – 703. While the expert was not allowed to opine as to whether defendant complied with FDA labeling requirements, he was allowed to testify about the facts and science regarding the risks and benefits of the drugs in question and to compare that knowledge with the labeling on the drugs. Id. at 702. Similarly in this case, because of his vast experience in FDA pre-approval issues and epidemiology Dr. Stolley should be permitted to opine on the standard of care for a pharmaceutical company's epidemiological analysis of clinical trial data. If the Court determines that he cannot testify about the proper epidemiological analysis that the Company "should' have undertaken, he should be permitted to testify about the industry standard for epidemiological analysis, and to compare that analysis with the analysis performed by the Company.

As described above, Lead Plaintiff will offer Dr. Stolley for his testimony about pharmaceutical industry standards in the epidemiological analysis of clinical trial data. His testimony is not offered to prove that the Company engaged in unethical conduct, unlike in

Rezulin and Diet Drugs.[16] If the Court is concerned that use of the word "ethics" will be prejudicial, counsel and the witness can easily be directed not to use the word.[17]

B. Dr. Stolley's Opinion Should not be Excluded as Prejudicial

In Paoli II, 35 F.3d 717 (3d Cir. 1994) the Court said that when balancing the reliability of expert testimony against the possibility that admitting the evidence would overwhelm, confuse or mislead the jury, there is a presumption of helpfulness. Paoli II, 35 F.3d 746. The Court also said that the extent to which an adverse party has had notice and the opportunity to present his or her own experts is also relevant. The Court reiterated its opinion that in order for a district court to exclude scientific evidence, there must be something particularly confusing about the scientific evidence at issue. The Paoli II court also noted that the fact that Daubert held that Rule 702 is the primary locus of a court's gatekeeping role indicates that exclusion under Rule 403 should be rare. Paoli II, 35 F.3d at 747 fn. 16. Finally, the Paoli II court noted that "Rule 403 is rarely appropriate as a basis of *pre-trial* exclusion, because a judge cannot ascertain

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[16] In Garcia v. Columbia Med. Ctr. of Sherman, 996 F. Supp. 617 (E.D. Tex. 1998) the Court admitted expert testimony regarding medical ethics in order to inform the jury about the accepted standards of medical care which a reasonable health care provider would follow. This would help the jury determine whether defendants deviated from those standards, which would be relevant to plaintiff's negligence and gross negligence claims. 996 F. Supp. at 627-628.

[17] Unlike the experts in Rezulin, Dr. Stolley has extensive training and experience in the field of medical ethics. He has training in medical ethics from Johns Hopkins. He chaired the Ethics Committee for the Society for Epidemiological Research, which established ethical guidelines for epidemiologists working with the pharmaceutical industry. (Meth Ex. 6 128:12-129:4.) In his writings and articles he has discussed ethical problems in pre-approval studies. He has lectured on the ethics of pre-approval clinical trials nearly every time he has taught a course in pharmacoepidemiology over the past thirty years. Pharmaceutical companies send people who are going to be involved in clinical trials to take his courses in medical ethics and pre-approval medical ethics at Tulane and the University of Minnesota. (Meth Ex. 6 130:2-132:19.) He participated in developing the course in medical ethics for the University of Maryland School of Medicine. (Meth Ex. 6 134:17-135:23.)

potential relevance until that judge has a virtual surrogate for a trial record." Paoli II, 35 F.3d at 747.

In In re Paoli R.R. Yard PCB Litig., 916 F.2d 829 (3d Cir. 1990) ("Paoli I"), the Court said in the context of considering motions to exclude experts' testimony under Rule 403: "Moreover we stress that *pre-trial* Rule 403 exclusions should rarely be granted.… 'If … testimony survives the rigors of Rule 702 and 703 … Rule 403 is an unlikely basis for exclusion.' Excluding evidence as being more prejudicial than probative at the pretrial stage is an extreme measure that is rarely necessary, because no harm is done by admitting it at that stage." Paoli I, 916 F.2d at 859. (Internal citations omitted). Defendants' motion to exclude Dr. Stolley's opinions at this stage should be denied.[18]

As the Court noted in Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 596 (1993), vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate ways of challenging evidence. All of those means are available to Defendants. The extreme sanction of excluding expert testimony is neither necessary nor warranted in the case of Dr. Stolley. See also, 4 Jack B. Weinstein & Margaret A. Berger, Weinstein's Federal Evidence, § 702.02[5] (Matthew Bender 2d ed. 2005) "[M]any courts considering challenges to potentially confusing expert testimony under Rule 702 hold that, if the risk of confusion is not great, the potentially confusing nature of the testimony goes to the weight to be accorded to the evidence, and the proper course is to admit the expert

[18] Intertwined with Defendants' argument that Dr. Stolley's opinions should be excluded under Rule 403 is their argument that his opinion about Vanlev's safety is based on insufficient facts because he obtained his information about Vanlev's safety profile from BMS's summaries of the data. (Def. Mem. at 10.) Defendants do not claim that the data Dr. Stolley relied upon was wrong. The fact that he reviewed BMS's summaries rather than the thousands of pages of raw data does not render his opinion unreliable.

testimony and leave clarification to cross examination and the presentation of opposing expert testimony."

CONCLUSION

For the reasons set forth above, Lead Plaintiff respectfully requests that the Court deny Defendants' motion to strike the testimony of Dr. Stolley.

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